

VERSION WITH MARKINGS TO SHOW CHANGES MADE

On page 1, lines 10-12, the following changes were made:

This application [is related] claims benefit to U.S. provisional patent application [serial no.] 60/048,810, filed June 5, 1997, now abandoned [from which priority is claimed pursuant to 35 U.S.C. §119(e)(1) and which is incorporated] herein incorporated by reference in its entirety.

On page 8, lines 29-36, the following changes were made:

In another embodiment of the invention, antibodies or fragments thereof against the LS149 antigen can be used to detect or image [localizatiÔns] localizations of the antigen in a patient for the purpose of detecting or diagnosing a disease or condition. Such antibodies can be polyclonal or monoclonal, or made by molecular biology techniques, and can be labeled with a variety of detectable labels, including but not limited to radioisotopes and paramagnetic metals. Furthermore, antibodies or fragments thereof, whether monoclonal, polyclonal, or made by molecular biology techniques, can be used as therapeutic agents for the

-- REMARKS --

The specification has been amended to reflect the priority status of the present application. A clean version of the replacement paragraph has been provided and a version with markings to show changes made has also been provided in accordance with the Simplified Amendment Practice. Applicant respectfully requests that this objection be withdrawn.

The specification is objected to for a syntax error at page 8, line 30. This has been amended. A clean version of the replacement paragraph has been provided and a version with markings to show changes made has also been provided in accordance with the Simplified Amendment Practice. Applicant respectfully requests that this objection be withdrawn.

Correction of the specification is required regarding the use of trademarks. Applicant apologizes and respectfully requests that requirement of these corrections is held in abeyance until subject matter is deemed allowable.

The Examiner states that the parent application U.S. Application No. 60/048,810, filed June 5, 1997 does not disclose the specific fragments as set forth in the Amendment. Applicant respectfully disagrees.

Applicant indicated in the parent application that the sequences disclosed in the parent applications might also contemplate fragments of the sequences disclosed. Applicant respectfully requests permission to submit evidence, in the form of serial number, line number and page number pointing to support for an earlier filing date at a later time.

Claims 1-6, 11-12, 14, 16-25 and 30-34 are rejected under 35 USC §112, first paragraph because the specification does not provide enablement for the various polynucleotides and vectors with 50% identity. These claims have been cancelled.

Applicant respectfully submits that the specification includes disclosure of several methods for making and using polynucleotide sequences and variants. The specification defines the term "identity" and provides methods and techniques for making and using polynucleotides of varying percent identities and for calculating percent identity (*see* page 13). However, in an effort to expedite prosecution, new claims 35-45 do not include percent identity language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 14 16-34 are rejected under 35 USC §101, because the claimed invention is not supported by a specific asserted utility or well established utility. The Examiner states that the specification teaches general utility for the invention, not a specific utility. These claims have been cancelled.

Furthermore, Applicant respectfully traverses this rejection. Applicant asserts that previously submitted arguments show a well-established utility and an asserted utility for the claimed invention. The specification teaches that the claimed gene products detected themselves in lung samples but not in non-lung RNA samples, thereby establishing that lung tissue is the host tissue of the claimed gene products. Applicant further clarifies that the detection of the claimed gene products OUTSIDE their host lung tissue, is diagnostically useful. Thus, presence of the claimed gene products outside normal host tissue serves as a diagnostic indicator that the host tissue is in a diseased state. → *NV 1 partis*

The polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existent. Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case lung tissue) into other areas of the body. Thus, these polynucleotides are useful as markers for the detection of disease in lung tissue.

The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the “definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). The utility of gene products such as those claimed in the present invention are established in the art. Therefore, Applicant asserts that the examples and methods disclosed in the specification are useful for detecting, at the least, lung diseases that may be detected using gene markers and related gene marker technology.

Based on the above, it is clear that the presence or absence of gene products that are expressed in the body is of diagnostic significance for cancer in a manner consistent with the methods and products claimed in the new claims. Thus, the claimed polynucleotides of the present invention exhibit credible utility for several genres of tests well known in the art, whether direct or indirect in nature. Applicant respectfully submits the new claims are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-4 and 22-25 are rejected under 35 USC §112, second paragraph as indefinite. These claims have been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 14, 16-25 and 27-34 are rejected under 35 USC §112, first paragraph as containing subject matter which is not described in the specification in such a way as to convey to one skilled in the art that the inventors were in possession of the claimed invention at the time of filing. These claims have been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 34 is rejected under 35 USC §102(b) as being anticipated by *Kubota et al.* which teaches a polynucleotide with at least 50% identity to nucleotides 5-419 of SEQ ID NO:7. This claim has been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 14 is rejected under 35 USC §102(b) as being anticipated by *Chen et al.* which teaches a polypeptide fragment having at least 50% identity to SEQ ID NO:7. This claim has been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 5-6, 16-21 and 27-29 are rejected under 35 USC §102(b) as being anticipated by *Bonaldo et al.* which teaches a recombinant expression vector having a nucleic acid sequence with at least 50% identity with nucleotides 51-284 of SEQ ID NO:7. These claims have been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claim 11 is rejected under 35 USC §102(b) as being anticipated by *Attie et al.* This claim has been cancelled. New claims 35-45 do not contain “percent identity” language. Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Serial No.: 09/092,296
Filed: June 5, 1998
Case No.: 6104.US.01
Page 11

CONCLUSION

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Dated: August 13, 2001

Respectfully submitted,
P.A. Billing-Medel, *et al.*

ABBOTT LABORATORIES
D-0377/AP6D-2
100 Abbott Park Road
Abbott Park, Illinois 60064-6050
Phone: (847) 935-7550
Fax: (847) 938-2623

Mimi C. Goller
Registration No. 39,046
Attorney for Applicants

CARDINAL LAW GROUP
1603 Orrington Avenue
Suite 2000
Evanston, Illinois 60201
Tel: (847) 905-7111
Fax: (847) 905-7113

Ruth Pe Palileo
Registration No. 44,277
Agent for Applicants